

Amendment and Response

Applicant: William J. Bertrand et al.

Serial No.: 10/698,117

Filed: October 31, 2003

Docket No.: M190,247,101 / P0011522.00

Title: INDICATOR TOOL FOR USE WITH AN IMPLANTABLE MEDICAL DEVICE

IN THE SPECIFICATION

Please add the following two paragraphs after Paragraph [0007]:

An example of a fluid control device is shown in U.S. Pat. No. 5,637,083 issued to William J. Bertrand and David A. Watson on Jun. 10, 1997 entitled "Implantable Adjustable Fluid Flow Control Valve," the teaching of which is incorporated herein in its entirety by reference. The valve of the '083 patent is shown in FIGS. 1-2 generally labeled 10 (20). (Reference numbers in parentheses correspond to the reference numbers in the '083 patent. After the corresponding reference number to the '083 patent has been given once, no further reference to the '083 will be given although the connection to the '083 patent is intended to be implied throughout this description.) The valve 10 includes an inlet connector 12 (22) and an outlet connector 14 (24). An elastomeric casing 16 (30) covers the inner workings of the valve 10. A dome 18 (60) extends upward from the elastomeric casing 16. Fluid flows through the valve 10 in the direction indicated by the arrow "A."

Valve 10 includes a mechanism to control fluid flow through the valve 10. The mechanism includes a magnet 20 (120) embedded within a base 22 (122). Rotating the base 22 changes the internal configuration of the mechanism. Changing the internal configuration of the mechanism produces a variety of pressure or flow characteristics for the valve. The base 22 may be rotated by magnetically coupling an external magnet 24 (140) to the valve's magnet 20 and rotating the external magnet 24. Because magnet 20 is coupled to the external magnet 24, when magnet 24 rotates, magnet 20 also rotates. As magnet 20 rotates, base 22 rotates and the internal configuration of the mechanism changes as described in detail in the '083 patent. As the internal configuration of the valve 10 changes, the pressure/flow characteristics of the valve 10 change. In use, the valve 10 is subcutaneously placed on the patient's skull. The catheter going to the patient's ventricle is attached to inlet connector 12. The catheter going to the patient's peritoneal cavity or vascular system is attached to outlet connector 14. In this way, a direction of flow is

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established from the inlet connector 12 through the valve 10 to the outlet connector 14. As stated above and described in detail in the '083 patent, changing the internal configuration of the mechanism by coupling the external magnet to the internal magnet and rotating the base produces a variety of pressure or flow characteristics through the valve 10.

Please delete Paragraph [0054] and replace with the following:

In the embodiment of FIG. 6A and 6B, the compass module of the indicator tool 605 is used to generate magnetic field data for both ambient background magnetic fields and target magnetic fields. The locator tool 600 is held away from a patient with the indicator tool 605 in its proper place when magnetic field data is obtained for just the ambient background magnetic fields. This data is stored within the locator tool 600. The locator tool 600 is next placed over the implanted flow control with the indicator tool 605 in place over its corresponding indicator position 603 and a second reading is obtained. The second reading corresponds to the magnetic fields that are a combination ambient background magnetic fields and target magnetic fields as discussed above. The locator tool 600 processes these two magnetic fields data values as described above to obtain the setting for the valve within the implanted flow control device.

Please delete Paragraph [0055] and replace with the following:

The electronic modules within the devices as shown in FIG. 6B perform the functions described above in regards to FIG. 4. The background magnetic fields data is generated by the compass module 622 in the indicator tool 601 and transmitted to the compass control module 620 and then through the communications channel of the interface modules 613, 623 for storage within the processing module 610. Once the tools are placed over an implanted flow control device, the compass module 622 generated additional data that is again transmitted to the processing module 610. The two sets of magnetic field data is processed in the processing module 610 to generate a setting value for the valve in the flow control device and the setting data is displayed to a user on

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the display module 611. The adjustment tool 602 may be used as discussed below to change a setting for the valve as desired. The valve position detection process may be repeated once the valve has been adjusted to verify the new setting for the valve.

Please delete Paragraph [0056] and replace with the following:

FIG. 7B is another embodiment of a block diagram illustrating internal electronic modules used in implementing an embodiment of the indicator and locator tool 705. In this embodiment, the electronics for the compass module 722, processing module 710, and display module 711 are all located within the indicator tool 701. The compass module 722 measures the magnetic fields for both the ambient background fields as well as the target magnetic field and communicates the data to the processing module 710 via the compass control module 720. Because all of these electronic modules are located within the indicator tool 701, a communications channel and corresponding interface modules are not needed. This embodiment places the electronic display 711 from the locator tool 700 to the indicator tool [[701]] 705 over its corresponding indicator position 703 as shown in FIG. 7A. The adjustment tool 702 may be used as discussed below to change a setting for the valve as desired.

Please delete Paragraph [0058] and replace with the following:

FIG. 8 illustrates a diagram of an improved locator tool while used with an accompanying adjustment tool in accordance with an example embodiment of the present invention. Once the current position of the valve is determined and displayed on display module 811, the adjustment tool 805 may be used to alter the setting for the valve within the flow control device. The adjustment tool 805 corresponds to a magnetic coupling device that is placed over the locator tool 800 to orient the adjustment tool 805 directly over the magnetic indication device 801 that is part of the valve. The adjustment tool 805 magnetically couples to the magnetic indication device 801 such that a rotation of the adjustment tool 805 causes the magnetic indication device

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to rotate within the valve. This rotation of the magnetic indication device 801 changes the settings for the valve within the flow control device as the magnetic indication device 801 is directly coupled to the valve setting mechanism. The operation of the adjustment tool 805 is disclosed in additional detail with the published U.S. patent application to Bertrand et al., No. 2002/0022873 as identified above.